

Applicant: Rashid A. Fawwaz
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REMARKS

Claims 1-26 are pending and under examination in the subject application. Applicant has canceled claims 5, 6, and 22-26 without disclaimer or prejudice to applicant's right to pursue the subject matter of these claims in the future. Applicant has also amended claim 1 in order to more particularly point out that which the applicant regards as the invention. Support for the amendment to claim 1 can be found in the specification at, *inter alia*, page 6, line 3 and page 9, lines 8-15. Applicant maintains that this Amendment raises no issue of new matter. Accordingly, upon entry of this Amendment, claims 1-4 and 7-21 will be pending and under examination.

Objection to the Specification

The Examiner objected to the specification on page 10, line 18 which refers to "Table I".

In response, applicant has amended the specification such that the specification at page 10, line 18 does not refer to "Table I". Accordingly, applicant respectfully requests that the Examiner withdraw this objection.

Nucleotide and/or Amino Acid Sequence Requirements

A Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures was included with the October 20, 2006 Office Action. The Notice alleges that the subject specification fails to comply

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with the requirements of 37 C.F.R. §§1.821-1.825, and states that that applicant must provide (i) a paper copy of the sequence listing and an amendment directing its entry into the application, (ii) a computer readable form ("C.R.F.") of the sequence listing and (iii) a Statement in Accordance with 37 C.F.R. §1.821(f) certifying that the C.R.F. and the paper copy of the sequence listing contain the same sequence information. A copy of the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures is attached hereto as **Exhibit A**.

Applicant submits herewith (i) a paper copy of the Sequence Listing (**Exhibit B**), (ii) a C.R.F. of the Sequence Listing and (iii) a Statement in Accordance with 37 C.F.R. §1.821(f) certifying that the C.R.F. and written sequence listing contain the same sequence information (**Exhibit C**). Applicant has also amended the specification to incorporate the sequence listing.

Rejections under 35 U.S.C. §102

The Examiner rejected claims 22, 23 and 25 under 35 U.S.C. §102(b) as allegedly anticipated by Fawwaz, et al. for reasons set forth in the Office Action.

In response, and without conceding the correctness of the Examiner's rejection, applicant notes that claims 22, 23 and 25 have been canceled. Accordingly, the Examiner's rejection thereof is moot.

The Examiner further rejected claims 22-26 under 35 U.S.C. §102(b)

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as alleged anticipated by U.S. Patent No. 5,861,156 ("George, et al.") for the reasons set forth in the Office Action.

In response to this rejection, applicant notes that claims 22-26 have been canceled. Accordingly, the Examiner's rejection is moot.

The Examiner further rejected claims 1, 22, 23 and 25 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,328,985 ("Sano, et al."). Specifically, the Examiner alleged that Sano, et al. teaches a recombinant streptavidin-Protein A chimeric protein and the use of this protein for the prevention or treatment of infection in transplant recipients. While acknowledging that Sano, et al. does not teach that the purpose of administering the chimeric streptavidin protein is for inhibiting transplant rejection, it is a general rule that merely discovering and claiming a new benefit to an old process cannot render the process patentable. The Examiner further stated that Sano, et al. teaches the same method steps as the instant method including administration to a transplant recipient and, as such, anticipates claim 1 (and now canceled claims 22, 23 and 25).

In response to the rejection of claims 22, 23 and 25, applicant notes that these claims have been canceled. Accordingly, the Examiner's rejection thereof is moot.

In response to the rejection of claim 1, applicant respectfully disagrees.

As an initial matter, applicant notes that claim 1 has been amended to recite "allogenic" transplant by incorporating the feature

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previously recited in claim 5. For this reason alone, the rejection under 35 U.S.C. §102(b) is no longer applicable.

In addition, applicant notes that Sano, et al. uses a conjugate of recombinant streptavidin-Protein A chimeric protein antibody to treat or prevent infection wherein the antibody is the anti-infective agent present in the complex. Such a conjugate is a different chemical entity from streptavidin *per se*.

Still further, claim 1, as amended, recites that the streptavidin is administered in an amount effective to inhibit immunological rejection of the transplant. Sano, et al. neither uses streptavidin *per se* nor discloses an amount effective to inhibit immunological rejection of the transplant.

For the preceding reasons, claim 1, as amended, is not anticipated by Sano, et al.

In view of the above remarks, applicant respectfully requests that the Examiner reconsider and withdraw all of the rejections under 35 U.S.C. §102.

Rejection under 35 U.S.C. 112, First Paragraph

The Examiner rejected claims 1-26 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. While acknowledging that the specification is enabling for methods of delaying the rejection of an allograft in a subject comprising transplanting an allogeneic tissue or organ to a subject and administering by intraperitoneal injection 20 mg/kg of streptavidin for five

consecutive days starting on the day of the transplant, the Examiner alleges that specification does not reasonably provide enablement for inhibiting the rejection of any transplant comprising administering at any time before or after transplantation of an organ, tissue or cells, any amount of streptavidin using any route of administration.

In response to the rejection of claims 5, 6 and 22-26, applicant notes that these claims have been canceled. Accordingly, the Examiner's rejection thereof is moot.

In response to the rejection of the remaining claims, applicant respectfully disagrees.

The Examiner's rejection, in part, alleges that the specification is not enabling for a method of inhibiting rejection of any transplant.

In response, applicant notes that claim 1, as amended, recites, in relevant part, a method for inhibiting the immunological rejection of an allogenic transplant in a subject, which the Examiner has conceded is enabled by the specification.

Applicant further notes that claim 1, as amended, recites administering to the subject, at a suitable time after transplant, an amount of streptavidin effective to inhibit immunological rejection of the transplant. The Examiner has acknowledged that a method wherein 20 mg/kg body weight of streptavidin is administered intraperitoneally to a subject 1-5 days post-transplant is enabled. Applicant maintains that based on this example, the specification

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as a whole and the knowledge of those skilled in the art, one skilled in the art would be able to determine, without undue experimentation, suitable periods of time after an allogenic transplant for administering an amount of streptavidin effective to inhibit rejection of the transplant by other routes of administration.

In view of the preceding remarks, applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §112, first paragraph.

Summary

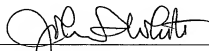
For the reasons set forth above, applicant maintains that pending claims 1-4 and 7-21 are in condition for allowance, and respectfully request that the Examiner issue a notice of allowance with respect to such claims.

No fee, other than the enclosed \$510.00 fee for a three-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

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If a telephone interview would be of assistance in advancing the prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

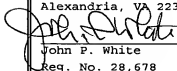
Respectfully submitted,



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